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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,976	09/27/2001	David A. Ferrick	A-66038-4/RMS/JJD/DLR	7248
959	7590	07/12/2004	EXAMINER MURPHY, JOSEPH F	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,976	FERRICK ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29, 30 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 33-36, 38-40 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

Claims 29-30, 33-40 are pending. Claim 30 is withdrawn from consideration pursuant to 37 CFR 1.142(b).

Response to Amendment

Applicant's arguments filed 04/29/2004 have been fully considered but they are persuasive in part, for the reasons set forth below.

The rejection of claims 29, 31-35 under 35 USC § 112 second paragraph for recitation of the term "2a site" has been withdrawn based on Applicant's arguments.

The rejection of claim 34 under 35 USC § 112 second paragraph for the recitation of the term "death gene" has been withdrawn based on Applicant's arguments.

The rejection of claims 29, 31, 35 under 35 U.S.C. 102(b) as being anticipated by Iida et al. (1996) has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 29, 31-35 under 35 U.S.C. 103(a) as being unpatentable over Iida et al. (1996) in view of Mikita et al. (1997), further in view of Persons et al. (1997), and further in view of U.S. Patent No. 5,834,266, (Crabtree et al.), has been obviated by Applicant's amendment and is thus withdrawn.

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Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 31-35 stand rejected, and new claims 36, 38-40 are rejected, under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for a retroviral vector comprising a fusion nucleic acid comprising: i) an IL-4 inducible epsilon promoter with the sequence as set forth in SEQ ID NO: 1; ii) a first reporter gene; iii) a nucleic acid encoding a 2a site; and iv) a second reporter gene, does not reasonably provide enablement for a retroviral vector comprising a fusion nucleic acid comprising: i) an inducible promoter or an IL-4 inducible epsilon promoter; ii) a first reporter gene; iii) a nucleic acid encoding a 2a site; and iv) a second reporter gene, for reasons of record set forth in the Office Action of 01/14/2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of record set forth that the claims encompass retroviral vectors comprising inducible promoters or an IL-4 inducible epsilon promoter. The claims as written thus encompass all inducible promoters, while only providing one example, and the term IL-4 inducible promoter is defined in the specification as encompassing derivatives (see page 8, lines 24-25). Applicant only discloses an IL-4 inducible epsilon promoter of SEQ ID NO: 1. Since the claims encompass variant nucleic acids, it would require undue experimentation to make and use the claimed invention. Applicant has amended the claims to recite that the promoter of interest is an IL-4 inducible promoter, and argues that variants of the IL-4 inducible promoter

can be constructed and then tested for functionality. However, Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass promoters that the specification only teaches one skilled in the art to test for functional variants to be used in the claimed vector. It would require undue experimentation for one of skill in the art to make and use the claimed vectors, since the skilled artisan would have to first make variants of the IL-4 inducible promoter, then test for function. Thus, since Applicant has only taught how to test for variants of IL-4 inducible promoter, and has not taught how to variants of IL-4 inducible promoter, it would require undue experimentation of one of skill in the art to make and use the claimed vector.

Claims 29, 31-35 stand rejected, and new claims 36, 38-40 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Action of 1/14/2004. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. These are genus claims. The claims encompass retroviral vectors comprising inducible promoters or an IL-4 inducible epsilon promoter. The claims as written thus encompass all inducible promoters, while only providing one example, and the term IL-4 inducible promoter is defined in the specification as encompassing derivatives (see page 8, lines 24-25). Applicant

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only discloses an IL-4 inducible epsilon promoter of SEQ ID NO: 1. Applicant has amended the claims to recite that the promoter of interest is an IL-4 inducible promoter, and argues that variants of the IL-4 inducible promoter can be constructed and then tested for functionality. However, In *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 USC 112, 1st paragraph, if only a few of the sequences that meet the functional limitations of the claim are disclosed and if undue experimentation would be required of one skilled in the art for determining other genetic sequences embraced by the claim. In the instant case there are a large number of nucleic acid sequences which are possible IL-4 inducible promoters, while the specification provides the necessary guidance to make the vector with the promoter of SEQ ID NO: 1, it does not provide the necessary guidance for one of skill in the art to use the vectors which do not encode function as an IL-4 inducible promoter. Further, since no functional language is associated with the vector, one of ordinary skill in the art would not know how to use these defined sequences except in further characterization of the sequences themselves.

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time the invention was made, it would have required one of skill in the art undue experimentation to practice the invention as claimed.

Conclusion

Claims 29, 33-36, 38-40 are rejected.

Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
July 1, 2004